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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,429	09/02/2004	Tsutomu Furuzono	1035-526	1242

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EXAMINER	
PENG, KUO LIANG	
ART UNIT	PAPER NUMBER
1796	
MAIL DATE	DELIVERY MODE
03/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,429	FURUZONO ET AL.	
	Examiner	Art Unit	
	Kuo-Liang Peng	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/29/08 RCE*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-8 and 18* is/are allowed.

6)☒ Claim(s) *9,11,13-17,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 29, 2008 has been entered. Claims 10 and 12 are deleted. Claims 9, 11, 19 and 20 are amended. Now, Claims 1-9, 11 and 13-20 are pending.

2. The text of those sections of Title 35, U.S. code not included in this action can be found in prior Office Action(s).

Claim Rejections - 35 USC § 102 and 103

3. Claims 9, 11, 13-17 and 19-20 are rejected as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP511 (JP 2001-172511) as evidenced by Sato (US 4 276 135)

For Claims 9 and 11, JP511 discloses a hydroxyapatite complex prepared by a manufacturing method where a hydroxyapatite sintered compact is bonded to a polymer via urea or urethane linkages. The urea or urethane linkages can be

derived from a reaction between an isocyanate functional group and an amino or hydroxyl group. ([0011]-[0013], [0016], [0023], [0037] and [0043]) The hydroxyapatite can contain an amino group by treated with a silane coupling agent such as KBE903. ([0043] and [0049]) In addition, Sato teaches that KBE903 is **3-aminopropyl triethoxysilane**. The polymer can be surface treated to introduce active groups, followed by grafting through the active groups with ethylenic monomers containing functional groups for reacting with the hydroxyapatite. ([0044]) The polymers can be polysiloxane, etc. that are medical polymeric materials. ([0012] and [0044]) The hydroxyapatite complex can be used for preparing percutaneous trans-catheter, percutaneous terminal, artificial blood vessel and artificial organ. ([0047]) JP511 is silent on the use of the claimed **alkoxysilyl group**-containing polymer. However, the instant claims are product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" *In re Thorpe*, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). "The Patent Office bears a lesser burden of proof in making out a case

of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a **product-by-process** claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is **not equipped** to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688

(CCPA 1972). For Claims 13-17 and 19-20, as mentioned above, the hydroxyapatite sintered compact is treated with KBE903. As such, the hydroxyapatite complex comprises the structure (1) set forth in the instant claims.

For Applicants' argument (Remarks, page 9, 2nd paragraph to page 10, last paragraph), Examiner does not dispute that JP511's hydroxyapatite complex is made by a process different than that of the instant claims where no active group is introduced to the hydroxyapatite sintered compact. However, first, Applicants has not yet proved that JP511's reacted hydroxyapatite sintered compact has residual functional groups. Second, Applicants has not demonstrated a method where all the alkoxysilyl groups on the modified polymer-based material are reacted with the hydroxyapatite, either. Notably, if there are residual alkoxysilyl groups after reacting the hydroxyapatite with the alkoxysilyl groups on the polymer-base material, then, the surface of the reacted hydroxyapatite clearly contains "active groups". As such, it appears that the limitation "a hydroxyapatite sintered compact into which no active group is introduced" will **not necessarily** result in a hydroxyapatite complex **free of** active group on the reacted hydroxyapatite sintered compact. This would rendered Applicants' alleged advantage recited in the specification (page 7, lines 12-18) irrelevant.

4. Claims 9, 11 and 19-20 are rejected as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hino (US 5 814 681).

For Claims 9 and 11, Hino discloses a hydroxyapatite complex prepared by chemically bonding a hydroxyapatite sintered compact with a polymer. (col. 2, lines 8-49, col. 3, lines 29-34, col. 3, line 61 to col. 4, line 4) The hydroxyapatite can be surface treated using **γ-methacryloxypropyltrimethoxysilane,** etc. to afford polymerizable groups on the surface thereof. (col. 4, lines 5-39) The hydroxyapatite complex can be used as a medical material. (col. 1, lines 6-9) Hino is silent on the use of the claimed **alkoxysilyl group**-containing polymer. However, the instant claims are product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" *In re Thorpe*, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). "The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324,

326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a **product-by-process** claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is **not equipped** to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). For Claims 13-17 and 19-20, as mentioned above, the hydroxyapatite sintered compact is treated with KBE903. As such, the hydroxyapatite complex comprises the structure (1) set forth in the instant

claims. For Claims 19-20, as mentioned above, the hydroxyapatite sintered compact is treated with γ-methacryloxypropyltrimethoxysilane. As such, the hydroxyapatite complex comprises the structure (1) set forth in the instant claims.

For Applicants' argument (Remarks, page 9, 2nd paragraph to page 10, last paragraph), Examiner does not dispute that Hino's hydroxyapatite complex is made by a process different than that of the instant claims where no active group is introduced to the hydroxyapatite sintered compact. However, first, Applicants has not yet proved that Hino's reacted hydroxyapatite sintered compact has residual functional groups. On the contrary, Hino's "active groups" (e.g., methacryloxy) are co-polymerized with commoners as illustrated in col. 4, lines 5-62. Especially, the comonomers recited therein are typically liquid at the polymerization temperature, they should have intimate contact with the "active groups" on the modified hydroxyapatite so that all active groups are reacted/polymerized. Second, Applicants has not demonstrated a method where all the alkoxysilyl groups on the modified polymer-based material are reacted with the hydroxyapatite, either. Notably, if there are residual alkoxysilyl groups after reacting the hydroxyapatite with the alkoxysilyl groups on the polymer-base material, then, the surface of the reacted hydroxyapatite clearly contains "active groups". As such, it appears that the limitation "a hydroxyapatite sintered compact into which no active group is

introduced" will **not necessarily** result in a hydroxyapatite complex **free of** active group on the reacted hydroxyapatite sintered compact. This would rendered Applicants' alleged advantage recited in the specification (page 7, lines 12-18) irrelevant.

5. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hino in view of JP511.

Hino discloses a medical material, supra, which is incorporated herein by reference. Hino is silent on the specific medical articles set forth in the instant claims. However, JP511 teaches a hydroxyapatite complex as a medical material used for preparing percutaneous trans-catheter, percutaneous terminal, artificial blood vessel and artificial organ. ([0047]) Note that Hino's polymer contains polyo**xyalkylene** and **methacryl** moieties. (col. 2, lines 16-49) JP511's polymer can contain poly**oxyalkylene** and poly**(meth)acrylate**.([0012]) Since Hino's medical material is substantially the same as that of JP511's, it would have been obvious to one of ordinary skilled in the art at the time of the invention was made to utilize Hino's medical material for making JP511's medical articles with expected success. Especially, Hino is in the same field as that of JP511's endeavor.

Allowable Subject Matter

6. Claims 1-8 and 18 are allowed.

7. The following is an examiner's statement of reasons for allowance:

None of the above references, taken alone or in combination, teaches or fairly suggest a) the manufacture **method** of a hydroxyapatite complex where an **alkoxysilyl group**-containing polymer-based material is used as set forth in Claims 1-8; and b) the manufacture method of a hydroxyapatite complex where a hydroxyapatite sintered compact is reacted with an **isocyanate** group of **silk fibroin** as set forth in Claim 18.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (571) 272-1091. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Seidleck, can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

klp
February 28, 2008

/Kuo-Liang Peng/
Primary Examiner, Art Unit 1796